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10/716,641

11/18/2003

Joseph C. Eder

03-168 (US01)

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10/10/2006

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EXAMINER

SOOHOO, TONY GLEN

ART UNIT

PAPER NUMBER

1723

DATE MAILED: 10/10/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/716,641

Applicant(s)

EDER ET AL.

Examiner

Tony G. Soohoo

Art Unit

1723

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on RCE filed 8-18-2006.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 2-4 and 10-48 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 5-9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

**DETAILED ACTION**

***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 5-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are inconsistent in the use of terminology thereby renders the claim unclear if the claim is referring to the same element or introducing a new element. Examples are: "the housing having respective proximal and distal openings", "the proximal opening", "the proximal housing opening", "the proximal opening of the mixing chamber", "the distal housing opening".

3. Claims 1, 5-9 recites the limitation ""the distant housing opening" in claim 1. There is insufficient antecedent basis for this limitation in the claim. The claim only states "the housing", "proximal and distal openings" (plural).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 15-9 are rejected under 35 U.S.C. 103(a) as being unpatentable Handler 4676655 in view of Ronk 5951160.

Handler shows a housing, a mixing chamber in 12, 14, distal opening 24,

Note: disc with perforations 128, 139 , and blades 131, figs 8-9, 101 and coupling means 165, 164, 166, which couples the piston 52 to the rod 101 at 165, or see the uncoupled configuration at the top of figure 4 and the coupled configuration at the bottom of figure 4 when the latch operators 67 is moved.

The Handler reference discloses all of the recited subject matter as defined within the scope of the claims with the exception of an output valve in fluid connection with the distal housing opening. The recitation of *"[an output valve], the valve controllable to divert bone cement being dispensed form the chamber into one of a patient delivery lumen and a shunt lumen"* has been fully considered and deemed as being directed to the a function use of the valve. The valve is structurally "controllable" issues to the use with a bone cement or dispensing to a patient delivery lumen or shunt is beyond the claimed valve structure and does not further limit the valve structure. "a patient delivery lumen and a shunt lumen" and "bone cement" material has not been positively claims as part of applicant's invention.

The Ronk reference discloses that a chamber 16 with a piston delivery mechanism 56, 66 may be provided with a controllable valve 14, column 4, lines 4-40 connected to the distal housing opening at 58 so as to control the flow of material to another container such as 12.

In view of the teaching of Ronk that a piston plunger mechanism may be provided with a valve for selective delivery of the material from the chamber, absent any unexpected result, it is deemed that it would have been obvious to one of ordinary skill in the art to provide for the end of the distal discharge opening of the housing of the Handler device with a valve so that one may control the flow of the material flowing out of the opening.

### ***Response to Arguments***


6. Applicant's arguments filed 8-18-2006 have been fully considered but they are not persuasive. Applicant argues that each of the references does not have a output valve in communication with the housing, as now amended. In response not the feature of an output valve has been addressed in the rejection above.

### ***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tony G. Soohoo whose telephone number is (571) 272 1147. The examiner can normally be reached on 8AM-5PM, Tue-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Wanda Walker can be reached on 571-272-1151. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tony G Soohoo  
Primary Examiner  
Art Unit 1723